

## EXHIBIT 137

**From:** Shusterman, Neil  
**To:** Rotman, Harris; Chapman, Tara; Fetrow, Nancy  
**CC:** Davis, Matthew2; Collins, Mark  
**Sent:** 2/1/2017 7:39:30 PM  
**Subject:** FW: Opana ER Risk Management -- Suspicious Order Monitoring (SOM) program  
**Attachments:** SOM White Paper.pdf

This is from Lisa Walker in 2013. I think we should re-meet with her to understand where we are now in 2017.

Thanx, *Neil*

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**From:** Collins, Mark  
**Sent:** Tuesday, October 29, 2013 9:42 AM  
**To:** Shusterman, Neil  
**Subject:** Opana ER Risk Management -- Suspicious Order Monitoring (SOM) program

FYI

Regards, Mark.  
Office: 484.216.6746  
[REDACTED]  
Fax: 610-968-7135

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**From:** Walker, Lisa  
**Sent:** Tuesday, October 29, 2013 8:57 AM  
**To:** Collins, Mark  
**Subject:** RE: Opana ER Risk Management

Hi Mark –

To give you some background around the suspicious ordering activities (SOM) at Endo, I have outlined below our current process.

In Endo's SAP system, we have a limited SOM Program that looks at our buying (wholesalers) customers' 3 month and 12 month history and if any order is above the 3 or 12 month it goes on hold until it is reviewed by Customer Service. Once the orders are released in our system, they are sent to warehouse for processing, however, before they are release to ship, they are reviewed by UPS Supply Chain Solutions. UPS SCS is Endo's 3<sup>rd</sup> party distribution/warehouse partner. All of Endo's orders are shipped under UPS's DEA License, so UPS also performs their own SOM program. I have attached a document that outlines UPS's SOM program. Endo is auditing UPS SOM program next week.

Also, Endo is in the process of upgrading our SAP system next year. and as part of this upgrade, we developing a new robust SOM program for SAP. We can talk in detail about this upgrade when we meeting on Wednesday.

I hope this help in providing you with some background before our meeting.

Thanks,

Lisa

-----Original Appointment-----

**From:** Collins, Mark

**Sent:** Monday, October 28, 2013 10:06 AM

**To:** Collins, Mark; Walker, Lisa

**Subject:** Opana ER Risk Management

**When:** Wednesday, October 30, 2013 8:30 AM-9:00 AM (UTC-05:00) Eastern Time (US & Canada).

**Where:** Your Office

Hi Lisa:

As an action item from an OPANA ER Risk Management Team meeting, I'd like to meet with you to discuss what access we (Endo) have into any data streams that could provide insight into suspicious ordering activities.

Regards, Mark.

Office: 484.216.6746

Fax: 610-968-7135

DATE: 01/24/10

RE: SOM Executive Summary:

**Background:**

The purpose of the document is to provide an executive summary of the UPS SCS Suspicious Order Monitoring (SOM) program.

The U.S. Drug Enforcement Administration (DEA) requires registrants who distribute controlled substances to have a mechanism to identify and subsequently report all suspicious orders, as defined in 21CFR1301.74(b). As a DEA registrant at multiple Healthcare distribution centers, UPS SCS must comply with these requirements.

In face-to-face meetings, UPS SCS has described to DEA its third-party logistics provider role. DEA has been clear in its direction to UPS SCS about its responsibilities as a member of the registrant population. DEA expects UPS SCS to have a SOM program independent of any existing or future client SOM programs.

UPS SCS will make every effort to communicate and work in partnership with its clients to ensure that orders that call for DEA scheduled/listed drug products are properly evaluated and the determination of “suspicious” is arrived at with the appropriate input from the client and/or customer requesting the order. However, the ultimate responsibility of making “suspicious order” determination must reside with UPS SCS Regulatory Affairs to remain compliant with the DEA requirements.

**Industry Challenge:**

Though SOM requirements are not new to the industry, the parameters for determination of a suspicious order are not defined in a detailed manner within the regulations. Many companies use a threshold based approach. The DEA has stated that “threshold” based evaluations are insufficient to meet their SOM evaluation requirements. DEA requires a more advanced, statistical-based/defensible analysis of orders for scheduled/listed drugs.

**The UPS SCS Approach:**

The UPS SCS Quality Assurance (QA)/Regulatory Affairs (RA) department has worked with the UPS Business Information and Analytics (BIA) group to develop an algorithm for statistical analysis for controlled substance orders. The UPS BIA department includes PhD. statisticians who have developed a sophisticated algorithm, advanced enough to evaluate order quantity and frequency trends. In addition, the algorithm also evaluates order trends across like customers ordering these products and across the entire UPS SCS customer database ordering controlled substances.

The algorithm uses historical order data from the UPS SCS order management systems to run the calculations and evaluations against. The goal is to populate 24 months of historical data in the tool to run the algorithm evaluations against. The tool is not able to forecast order trends and can not take into account future business distribution events such as product promotions, volume ramp-up for product launches or other supply chain

anomalies. Therefore, there will always be a level of human evaluation by the RA department in conjunction with our clients to analyze such spikes to the historical trend.

Because of the magnitude of intellectual capital involved in having an industry-leading, non-threshold based solution for SOM, the algorithm, now embedded into the UPS SCS SOM tool, the associated Standard Operating Procedures (SOPs) and work instructions (WIs) are confidential and proprietary to UPS SCS and will not be shared with our client base or any party outside of UPS SCS. Detailed information would be shared with an agency inspector, if required. However, in the interest of our client's due diligence, this overview describes the SOM process, the basic concepts of the algorithm, and some of the business considerations in the evaluation period.

#### **Process Overview of SOM:**

1. Products in scope of the SOM program are Schedule II-V, List I chemicals and Iodine (of a certain DEA-specified concentration).
2. Products designated for SOM assessment are "flagged" in the UPS SCS order management systems (OMS), and put on hold until evaluated
3. Order information is processed in a timely fashion through the SOM evaluation tool by the RA group, prior to the order being released from hold and dropped for fulfillment to the warehouse.
  - a. Orders are evaluated based on DEA drug code, not the part or NDC number.
  - b. The SOM evaluation tool has four main criteria that are reviewed to determine release status:
    - i. Order Size
    - ii. Order Frequency
    - iii. Comparison of order quantities and frequency of similar customer type who order that drug code
    - iv. Comparison of order quantities and frequency of the entire UPS SCS customer base for that drug code
  - c. Each criteria described above will receive a color-coded result on the SOM tool Dashboard.
    - i. Green = Good, no issues
    - ii. Yellow = Caution, too few data points
    - iii. Red = Stop, order has possible issues
  - d. Orders with any of the four criteria returned as "red" or "yellow" are termed/designated as "orders of interest" (OoI) and require further evaluation.

#### **Evaluation of Orders of Interest:**

1. Orders receiving a Red or in some instances a Yellow result for one of the 4 evaluation criteria are deemed to be an (OoI).
2. The RA staff member who is evaluating the order is responsible for immediately escalating and communicating to both the Site Operations Contact and onsite Quality Assurance (QA) representative when orders that have failed for any reason. This avoids potential late order drop with no site awareness.

- a. The RA department is also responsible for researching and/or escalating failed orders to the client representative(s).
  - b. A contact list of RA, QA, Operations and Client contacts is maintained.
- 3. Internal Evaluations
  - a. Internal evaluations are conducted by RA to determine a reasonable explanation for an order of interest that may include, but are not limited to:
    - i. Confirmed sales/chargeback/promotions incentives
    - ii. Customer type information, such as destruction companies and repackers.
    - iii. Seasonality of product
    - iv. Potential keying errors
  - b. Based on a thorough evaluation, if the OoI is determined not to be suspicious, it will be released from hold by authorized RA personnel.
  - c. Any OoI released from hold will require appropriate documentation on a UPS SCS approved form and the appropriate release communications to Site Operations and onsite QA Representative.
- 4. External Evaluations
  - a. The client is expected to assist with external evaluation for all pended order that cannot be resolved with internal evaluations.
  - b. The RA department will again coordinate external evaluations with the client.
  - c. UPS SCS may not be aware of factors such as those mentioned in the Internal Evaluation section and will again need to be evaluated with client input. Other factors such as back-orders released by the client, new customers, or new facility openings of client's customers will also need to be taken into consideration.
  - d. The client may need to assist with contacting the customer whose order is in a pended status, based upon the level of Customer Service provided by UPS SCS or lack of contact information for that particular customer.
  - e. Based on thorough external investigation, the order is determined not to be suspicious; it will be released from hold by authorized UPS SCS personnel and documented on the appropriate, approved form.
  - f. Notification of the release will be made the appropriate UPS SCS personnel.
- 5. After thorough evaluations have been conducted and the order is deemed suspicious, the order must be canceled in the order management system and the appropriate agency notification made. Any agency communication will be documented and be provided to the client.